Bill – We have considered the questions you posed in your March 12 email. Our answers are in italics below. Please let us know by March 23 if you need additional information. Thanks.

Burton Craige and Kimberly Wilson

1. In what cases have drugs been removed from the market because of safety concerns as a result of FDA enforcement action and not because of private party product liability lawsuits?

To the best of our knowledge, no drug has ever been removed from the market because of safety concerns as a result of an FDA enforcement action.

2. In what cases have drugs been removed from the market because of private party product liability lawsuits and not because of FDA enforcement action?

This is a more difficult question to answer. The typical chain of events leading to a drug being withdrawn from the market goes something like this:

The FDA starts receiving adverse events data from consumers or physicians about a drug, for example, someone who had a heart attack while on Vioxx; a few lawsuits start to be filed across the country; press coverage about the lawsuits ensues; the FDA may insist upon a "label change"; the drug company and the FDA will "negotiate" about the substance of the label change; more lawsuits get filed; peer reviewed literature is published by the medical community raising concerns about a drug's safety profile; more adverse events are reported; more lawsuits are filed; more changes to the label are demanded by the FDA and ultimately a drug company will withdraw the drug from the market because it is no longer profitable to keep, or fight to keep, the unsafe drug on the market.

Or, it could go like this:

A label change is made and the dangerous drug remains on the market. For example, lawsuits start were filed after teenage girls died from blood clots caused by Yaz, babies were born without limbs to mothers who took Depakote during pregnancy, and otherwise healthy individuals developed type II Diabetes while taking Zyprexa. These unsafe drugs are still on the market after manufacturers implemented label changes mandated by the FDA in response to lawsuits.

In sum, when a drug is withdrawn or when the FDA orders a label change, a private party action is always one of the precipitating factors.

There are many examples of drug companies withholding valuable safety data from the FDA. For example, Merck withheld underlying data from Vioxx studies; AHP knew for years that women taking Pondimum were developing a fatal lung disease known as Primary Pulmonary Hypertension and went to great lengths to keep the FDA in the dark;

Bayer received information from unpublished studies about the increased risk of kidney failure in patients receiving Trasylol but failed to submit the information to the FDA. All of these facts came to light after litigation ensued.

3. In what cases, if any, has the FDA taken "final agency action" with regard to allegations of fraud by manufacturers?

We are aware of no such cases. If the pharmaceutical industry can cite examples, we would welcome the opportunity to consider them.

4. In a nationwide product liability class action lawsuit, what effect, if any, would the draft legislation before the subcommittee have on the legal rights of North Carolina residents who are members of the class?

A product liability class action against a drug manufacturer is exceedingly rare because individual consumers of prescription drugs do not meet the typicality and commonality prerequisites for class certification. Plaintiffs injured by dangerous prescription drugs almost always pursue their claims in individual actions. The proposed bill would block those lawsuits. In addition, it would prevent the Attorney General from pursuing claims for failure to warn and false and misleading advertising, leaving the State with no means to recoup many millions of dollars in Medicaid payments from drug manufacturers.